

Customer Number: 000959

Attorney's
Docket
Number CMZ-130

Declaration, Petition and Power of Attorney for Patent Application

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

NON-INVASIVE ENZYME SCREEN FOR TISSUE REMODELLING-ASSOCIATED
CONDITIONS

the specification of which

(check one)

 is attached hereto.

X was filed on October 15, 2001 as

Application Serial No. 09/977,878

and was amended on _____
(if applicable)

I do not know and do not believe that the subject matter of this application was known or used by others in the United States or patented or described in a printed publication in any country before my invention thereof, or patented or described in a printed publication in any country or in public use or on sale in the United States more than one year prior to the date of this application, or first patented or caused to be patented or made the subject of an inventor's certificate by me or my legal representatives or assigns in a country foreign to the United States prior to the date of this application on an application filed more than twelve months (six months if this application is for a design) before the filing of this application; and I acknowledge my duty to disclose information of which I am aware which is material to the examination of this application, that no application for patent or inventor's certificate on the subject matter of this application has been filed by me or my representatives or assigns in any country foreign to the United States, except those identified below, and that I have reviewed and understand the contents of the specification, including the claims as amended by any amendment referred to herein.

I acknowledge the duty to disclose to the Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

CLAIM OF BENEFIT OF EARLIER FOREIGN APPLICATION(S)

I hereby claim priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below, and have also identified below any foreign application(s) for patent or inventor's certificate filed by me on the same subject matter having a filing date before that of the application(s) from which priority is claimed.

Check one:

☒ no such applications have been filed.

☐ such applications have been filed as follows

EARLIEST FOREIGN APPLICATION(S), IF ANY, FILED WITHIN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

| Country | Application Number | Date of Filing (month,day,year) | Priority Claimed Under 35 USC 119 |
|---------|--------------------|------------------------------------|--|
| | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |

ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

| |
|--|
| |
| |
| |

CLAIM FOR BENEFIT OF U.S. PROVISIONAL APPLICATION(S)

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below.

60/240,489

(Application Serial No.)

October 13, 2000

(Filing Date)

(Application Serial No.)

(Filing Date)

CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S)

I hereby claim the benefit under Title 35, United States Code, §120 of any earlier United States application(s) or PCT international application(s) designating the United States listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the earlier application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose to the Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date(s) of the earlier application(s) and the national or PCT international filing date of this application. As to subject matter of this application which is common to my earlier application(s), if any, described below, I do not know and do not believe that the same was known or used by others in the United States or patented or described in a printed publication in any country before my invention thereof, or patented or described in a printed publication in any country or in public use or on sale in the United States more than one year prior to the date(s) of said earlier application(s), or first patented or caused to be patented or made the subject of an inventor's certificate by me or my legal representatives or assigns in a country foreign to the United States prior to the date(s) of said earlier application(s) on an application filed more than twelve months (six months if this application is for a design) before the filing of said earlier application(s); and I acknowledge that no application for patent or inventor's certificate on said subject matter has been filed by me or my representatives or assigns in any country foreign to the United States except those identified herein.

(Application Serial No.)

(Filing Date)

(Status)
(patented,pending,aband.)

(Application Serial No.)

(Filing Date)

(Status)
(patented,pending,aband.)

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorneys and/or agents to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

| | | | |
|------------------------|-----------------|---------------------|---------------------------|
| James E. Cockfield | Reg. No. 19,162 | Jeremiah Lynch | Reg. No. 17,425 |
| Thomas V. Smurzynski | Reg. No. 24,798 | David J. Ridders | Reg. No. 43,882 |
| Ralph A. Loren | Reg. No. 29,325 | Maria C. Laccotripe | Limited Recognition |
| Giulio A. DeConti, Jr. | Reg. No. 31,503 | | Under 37 C.F.R. § 10.9(b) |
| Ann Lamport Hammitte | Reg. No. 34,858 | Debra J. Milasincic | Reg. No. 46,931 |
| Elizabeth A. Hanley | Reg. No. 33,505 | David R. Burns | Reg. No. 46,590 |
| Amy E. Mandragouras | Reg. No. 36,207 | Sean D. Detweiler | Reg. No. 42,482 |
| Anthony A. Laurentano | Reg. No. 38,220 | Peter S. Stecher | Reg. No. 47,259 |
| Kevin J. Canning | Reg. No. 35,470 | Cynthia L. Kanik | Reg. No. 37,320 |
| Jane E. Remillard | Reg. No. 38,872 | Theodore R. West | Reg. No. 47,202 |
| DeAnn F. Smith | Reg. No. 36,683 | Shayne Y. Huff | Reg. No. 44,784 |
| Peter C. Lauro | Reg. No. 32,360 | Hathaway P. Russell | Reg. No. 46,488 |
| Jeanne M. DiGiorgio | Reg. No. 41,710 | Daniel B. Ko | Reg. No. 47,332 |
| Megan E. Williams | Reg. No. 43,270 | | |

Send Correspondence to Elizabeth A. Hanley, Esq. at Customer Number: 000959 whose address is:

Lahive & Cockfield, LLP, 28 State Street, Boston, MA 02109

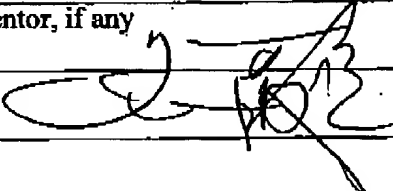
Direct Telephone Calls to: (name and telephone number)

Elizabeth A. Hanley, Esq., (617) 227-7400

Wherefore I petition that letters patent be granted to me for the invention or discovery described and claimed in the attached specification and claims, and hereby subscribe my name to said specification and claims and to the foregoing declaration, power of attorney, and this petition.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

| | |
|-------------------------------------|----------|
| Full name of sole or first inventor | |
| Marsha A. Moses | |
| Inventor's signature | Date |
| <i>Marsha A. Moses</i> | 12/12/01 |
| Residence | |
| 64 Dean Road, Brookline, MA 02146 | |
| Citizenship | |
| USA | |
| Post Office Address (if different) | |
| | |

| | |
|---|----------|
| Full name of second inventor, if any | |
| Li Yan | |
| Inventor's signature | Date |
|  | 12/14/01 |
| Residence | |
| 46 McClean Street, Wellesley, MA 02481 | |
| Citizenship | |
| P. R. of China | |
| Post Office Address (if different) | |

J Respir Crit Care Med 1997 Aug;156(2 Pt 1):677-8]. Am J Respir Crit Care Med 155, 1419-27.

- [81] Jarrard, J.A., Linnoila, R.I., Lee, H., Steinberg, S.M., Witschi, H. and Szabo, E. (1998) MUC1 is a novel marker for the type II pneumocyte lineage during lung carcinogenesis. *Cancer Res* 58, 5582-9.
- [82] Ohgami, A., Tsuda, T., Osaki, T., Mitsudomi, T., Morimoto, Y., Higashi, T. and Yasumoto, K. (1999) MUC1 mucin mRNA expression in stage I lung adenocarcinoma and its association with early recurrence. *Ann Thorac Surg* 67, 810-4.
- [83] Bejarano, P.A., Baughman, R.P., Biddinger, P.W., Miller, M.A., Fenoglio-Preiser, C., al-Kafaji, B., Di Lauro, R. and Whitsett, J.A. (1996) Surfactant proteins and thyroid transcription factor-1 in pulmonary and breast carcinomas. *Mod Pathol* 9, 445-52.
- [84] Harlamert, H.A., Mira, J., Bejarano, P.A., Baughman, R.P., Miller, M.A., Whitsett, J.A. and Yassin, R. (1998) Thyroid transcription factor-1 and cytokeratins 7 and 20 in pulmonary and breast carcinoma. *Acta Cytol* 42, 1382-8.
- [85] Fontanini, G., Vignati, S., Lucchi, M., Mussi, A., Calcinai, A., Boldrini, L., Chine, S., Silvestri, V., Angeletti, C.A., Basolo, F. and Bevilacqua, G. (1997) Neoangiogenesis and p53 protein in lung cancer: their prognostic role and their relation with vascular endothelial growth factor (VEGF) expression [see comments]. *Br J Cancer* 75, 1295-301.
- [86] Shibusa, T., Shijubo, N. and Abe, S. (1998) Tumor angiogenesis and vascular endothelial growth factor expression in stage I lung adenocarcinoma. *Clin Cancer Res* 4, 1483-7.
- [87] Giatromanolaki, A., Koukourakis, M.I., Kakolyris, S., Turley, H., O'Byrne, K., Scott, P.A., Pezzella, F., Georgoulas, V., Harris, A.L. and Gatter, K.C. (1998) Vascular endothelial growth factor, wild-type p53, and angiogenesis in early operable non-small cell lung cancer. *Clin Cancer Res* 4, 3017-24.
- [88] Fontanini, G., Boldrini, L., Vignati, S., Chine, S., Basolo, F., Silvestri, V., Lucchi, M., Mussi, A., Angeletti, C.A. and Bevilacqua, G. (1998) Bcl2 and p53 regulate vascular endothelial growth factor (VEGF)- mediated angiogenesis in non-small cell lung carcinoma. *Eur J Cancer* 34, 718-23.
- [89] Takahama, M., Tsutsumi, M., Tsujiuchi, T., Kido, A., Okajima, E., Nezu, K., Tojo, T., Kushibe, K., Kitamura, S. and Konishi, Y. (1998) Frequent expression of the vascular endothelial growth factor in human non-small-cell lung cancers. *Jpn J Clin Oncol* 28, 176-81.
- [90] Sozzi, G., Miozzo, M., Tagliabue, E., Calderone, C., Lombardi, L., Pilotti, S., Pastorino, U., Pierotti, M.A. and Della Porta, G. (1991) Cytogenetic abnormalities and overexpression of receptors for growth factors in normal bronchial epithelium and tumor samples of lung cancer patients. *Cancer Res* 51, 400-4.
- [91] Volm, M., Efferth, T., Mattern, J. and Wodrich, W. (1992) Overexpression of c-fos and c-erbB1 encoded proteins in squamous cell carcinomas of the lung of smokers. *Int J Oncol* 1, 69-71 1992.

- [156] Gotoh, K., Yatabe, Y., Sugiura, T., Takagi, K., Ogawa, M., Takahashi, T. and Mitsudomi, T. (1998) Frequency of MAGE-3 gene expression in HLA-A2 positive patients with non-small cell lung cancer. *Lung Cancer* 20, 117-25.
- [157] Uchiyama, B., Saijo, Y., Kumano, N., Abe, T., Fujimura, S., Ohkuda, K., Handa, M., Satoh, K. and Nukiwa, T. (1997) Expression of nucleolar protein p120 in human lung cancer: difference in histological types as a marker for proliferation. *Clin Cancer Res* 3, 1873-7.
- [158] Singh, G., Scheithauer, B.W. and Katyal, S.L. (1986) The pathobiologic features of carcinomas of type II pneumocytes. An immunocytologic study. *Cancer* 57, 994-9.
- [159] Mizutani, Y., Nakajima, T., Morinaga, S., Gotoh, M., Shimosato, Y., Akino, T. and Suzuki, A. (1988) Immunohistochemical localization of pulmonary surfactant apoproteins in various lung tumors. Special reference to nonmucus producing lung adenocarcinomas. *Cancer* 61, 532-7.
- [160] Noguchi, M., Nakajima, T., Hirohashi, S., Akiba, T. and Shimosato, Y. (1989) Immunohistochemical distinction of malignant mesothelioma from pulmonary adenocarcinoma with anti-surfactant apoprotein, anti-Lewis, and anti-Tn antibodies. *Hum Pathol* 20, 53-7.
- [161] Linnoila, R.I., Jensen, S.M., Steinberg, S.M., Mulshine, J.L., Eggleston, J.C. and Gazdar, A.F. (1992) Peripheral airway cell marker expression in non-small cell lung carcinoma. Association with distinct clinicopathologic features [see comments]. *Am J Clin Pathol* 97, 233-43.
- [162] Shijubo, N., Tsutahara, S., Hirasawa, M., Takahashi, H., Honda, Y., Suzuki, A., Kuroki, Y. and Akino, T. (1992) Pulmonary surfactant protein A in pleural effusions. *Cancer* 69, 2905-9.
- [163] Shijubo, N., Honda, Y., Fujishima, T., Takahashi, H., Kodama, T., Kuroki, Y., Akino, T. and Abe, S. (1995) Lung surfactant protein-A and carcinoembryonic antigen in pleural effusions due to lung adenocarcinoma and malignant mesothelioma. *Eur Respir J* 8, 403-6.
- [164] Nicholson, A.G., McCormick, C.J., Shimosato, Y., Butcher, D.N. and Sheppard, M.N. (1995) The value of PE-10, a monoclonal antibody against pulmonary surfactant, in distinguishing primary and metastatic lung tumours. *Histopathology* 27, 57-60.
- [165] Khor, A., Whitsett, J.A., Stahlman, M.T. and Halter, S.A. (1997) Expression of surfactant protein B precursor and surfactant protein B mRNA in adenocarcinoma of the lung. *Mod Pathol* 10, 62-7.
- [166] Saitoh, H., Shimura, S., Fushimi, T., Okayama, H. and Shirato, K. (1997) Detection of surfactant protein-A gene transcript in the cells from pleural effusion for the diagnosis of lung adenocarcinoma. *Am J Med* 103, 400-4.
- [167] Grohs *et al.*, *Acta Cytologica*, 1996, 40(1):26-30.
- [168] Grohs *et al.*, *Acta Cytologica*, 1997, 41(1):144-152.